

Attachment 2

**IN THE UNITED STATES PATENT AND TRADEMARK
OFFICE**

Patent Application No. 09/924,503)	
)	
Filed: August 9, 2001)	Art Unit: 3623
)	
Inventors: Matthew Barrer)	Examiner: Bachner, Rebecca M.
)	
)	
Title: METHOD OF IMPLEMENTING A)	Docket No.: 113175-00102
CARDIAC EMERGENCY READINESS)	
PROGRAM)	Date: March 17, 2003

DECLARATION OF SALLY J. HARRIS UNDER 37 C.F.R. §1.131

1. I am the General Manager of Brookside Country Club and held that position prior to May 8, 2000.
2. Prior to May 8, 2000, I met with Matthew Barrer and other employees and/or representatives of SafeMeetings to discuss a comprehensive cardiac emergency program which SafeMeetings was offering involving the use of "Automated External Defibrillators" which are sometimes referred to as AED's. My meetings with Mr. Barrer and others from SafeMeetings resulted in a letter and quote which was received prior to May 8, 2000, attached hereto as **Exhibit A**.
3. The program being offered by SafeMeetings involved "Project Management Support to Accomplish AED Program" including "Design, Implementation and Ongoing Performance Improvement".
4. SafeMeetings was offering to supply Brookside with an AED, specifically the "LIFEPAK 500 AED".
5. I understood that purchase of the services being offered by SafeMeetings prior to May 8, 2000, assured that Brookside's usage of any AED would be in accordance with all "Jurisdictional Laws."
6. Prior to May 8, 2000, I met with the House Committee of Brookside Country Club and a decision was made by the Committee to purchase the services of SafeMeetings including the purchase of initial AED training as set forth in a Brookside Country Club AED Implementation Plan". The House Committee also decided to place the AED to be purchased in the "closet in the rear wall of the Mens Grill," as recommended by SafeMeetings after Matthew Barrer and others had concluded a survey of the Brookside facilities.

7. I received my AED training prior to May 8, 2000 and was designated as a Director of the Program which required me to serve as a liaison with emergency medical specialists who could be summoned to the Brookside premises in the event of a cardiac incident.
8. Brookside's adoption of the program being offered by SafeMeetings prior to May 8, 2000, resulted in Brookside being included "in SafeMeetings.com AED Program Promotion in Publications and Educational Seminars".
9. The Brookside Country Club AED Implementation Plan offered by SafeMeetings provided that SafeMeetings would conduct an "evaluation and data management" as a follow-up to a cardiac "event."
10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information are believed to be true; and further that these statements are made with the knowledge that false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.


Sally J. Harris

3/17/03
Date

EXHIBIT A



Brookside Country Club
Sally J. Harris, General Manager
P.O. Box 311
Pottstown, PA 19464

Dear Sally:

Thank you for your interest in improving the standard of care that your club can provide to its members. The quote is broken down into an equipment price and a training price. As we discussed earlier today, it seems to be most practical to include training for AED use into the scheduled CPR training. I have scheduled the training with Mr. Biggs for the allotted time on Monday, If you find that the board will not agree to the difference in cost, we can provide CPR training alone. We can discuss that matter further on Monday, when we meet for the house committee meeting. If you have any further questions, feel free to call me at 610-659-8580.

Sincerely,

William L. Mest, P.A.-C.

CODE	QUANTITY	DESCRIPTION	COST
SafeMeetings.com Registry		* Recognition of Your AED Program at SafeMeetings.com	\$125.00
Seal of Approval		* Project Management Support to Accomplish AED Program Design, Implementation and Ongoing Performance Improvement (Pricing break for First U.S. YMCA Model)	\$250.00
		* Inclusion in SafeMeetings.com AED Program Promotion in Publications and at Educational Seminars	
		* Use of the SafeMeetings.com Icon to Promote Your AED Program	
Kit #2	1	LIFEPAK 500 AED with monophasic waveform, two button operation.	\$3156.00
		1 non-rechargeable battery,	
		1 spare pair electrodes (total of two)	
		1 carrying case,	
		and Ambu Res-Cue Key First Responder kit.	
LifeNet MD system	1	Medical Prescription – valid for years 2000-2005	\$495.00
Skills Maintenance	1	1 yr. SoftWare & Program Management	\$250.00
EQUIPMENT TOTAL:			\$4276.00
Training		Training According to Jurisdictional Laws CPR/AED including book for 12 persons	\$720.00
TOTAL:			\$4996.00

Attachment 3

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These search terms have been highlighted: **cardiac arrest survival act guidelines mandate**

Additional Information

PAD Program Legal Issues

State Laws Supporting Public Access Defibrillation

There have been no known lawsuits against lay rescuers providing CPR as Good Samaritans, nor any against AED users. However, the perceived potential for a suit against a lay rescuer using an AED has in some cases been a deterrent for companies or organizations considering establishing a public access defibrillation (PAD) program.

It's recommended that you check the laws in your state to determine any specific elements that may apply to your situation. Laws can often be researched via state Web sites. See www.csg.org for a list of states' Web sites. The state EMS Department (usually part of the State Health Department) can also provide information.

these states because their law does not provide limited immunity to the acquirer.)

- The limited immunity provided by the AED will benefit Maine and Columbia. (Maine and Iowa legislation that offers limited immunity to the user of the AED.)
- The limited immunity provided by the AED extends to private, public

2. **Placement of AEDs in Federal Buildings**
CASA calls for placement of AEDs in federal buildings. This is not a mandatory recommendation. Consider the development of implementation and guidelines for AEDs

The **Cardiac Arrest Survival Act (CASA)** was part of the Public Health Improvement Act signed into law in November 2000. The law directs placing automated external defibrillators (AEDs) in federal buildings and provides nationwide Good Samaritan protection that exempts from liability anyone who renders emergency treatment with a defibrillator to save someone's life.

Below is a thumbnail sketch of the two primary areas of CASA.

1. Extending Good Samaritan Protections:

CASA provides limited immunity to persons using the AED and the acquirer of the AED. It does not include limited immunity for the prescribing physician and the trainer.

- The limited immunity provision in CASA is a "gap filling" measure and does not supercede any existing state law that provides immunity for categories of people using AEDs.
- The limited immunity provision for the AED acquirer will benefit approximately 11 states and the District of Columbia. (It applies to

Assessing Your Legal

When considering the est PAD program, it's important I organization to consult its own. However, the following infornt taken into account:

- Cardiac arrest victims are es: dead. They lose consciouns and stop breathing in a matt moments. Most often the he contractions become ineffec spasms so the heart can't pu brain and the rest of the boc that can change this conditi. Using an AED can only hel
- Modern AEDs are safe and e The internal computer uses analysis algorithms to deter to shock. The AED will ma "shock" decision 90 out of a correct "no shock indicate more than 95 out of 100 tin of accuracy is greater than t emergency medical profess

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- To successfully sue an AED user or purchaser, four essential elements must be proven. These include duty, breach of duty, causation of injury and legally recognized damages. (Lazar, RA. Defibrillators Enter the Business Marketplace. *Occupational Health & Safety*. August, 1997). Common carriers (such as airlines, cruise ships, etc.), innkeepers, hotel and motel operators and commercial establishments open to the public do have special respon-sibilities defined by law to provide a minimum of care and common medical assistance.

A Changing Trend

As awareness of the new generation of AEDs grows, companies and organiz may face greater threat of liability if the aren't properly prepared to respond in a manner to a cardiac emergency. This tre can be seen in three cases in which laws were filed against companies that werer prepared. In 1996 Busch Gardens was f negligent for not being prepared and eq (including not having a defibrillator) to

and summon medical assistance.

- Training targeted rescuers in the AHA's Heartsaver AED course provides the essential knowledge of how to do CPR and use an AED. The course also has instruction on minimizing risks to the user and victim in unusual cases (such as when the victim is lying in a pool of water, has an implantable defibrillator or is on a metal surface).
- Most AED manufacturers offer some type of insurance to purchasers of their devices.

For companies and organizations considering having AEDs on site, a good offense may be the best defense. Implementing a public access defibrillation program that includes training lay rescuers in CPR and AED use, physician oversight, integrating with the EMS system and maintaining the AEDs according to the manufacturer's specifications establishes an intent to provide a safe and effective response to cardiac emergency.

to the cardiac arrest of a 13-year-old girl. Lufthansa Airlines was also found negligent because it failed to provide appropriate ment to a passenger who suffered a cardiac arrest. A similar lawsuit against United is now pending.

Attachment 4

[Federal Register: May 23, 2001 (Volume 66, Number 100)]
[Notices]
[Page 28495-28511]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr23my01-89]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

GENERAL SERVICES ADMINISTRATION

Guidelines for Public Access Defibrillation Programs in Federal Facilities

AGENCY: Office of Public Health and Science, Office of the Secretary, HHS and Office of Governmentwide Policy, GSA.

ACTION: Notice of availability of guidelines.

SUMMARY: The Department of Health and Human Services (HHS) and the General Services Administration (GSA) have worked collaboratively to develop the following guidelines, entitled "Guidelines for Public Access Defibrillation Programs in Federal Facilities." These guidelines were prepared, in part, in response to a May 19, 2000, Presidential Memorandum pertaining to the establishment of guidelines for the placement of automated external defibrillators (AEDs) in Federal buildings.

In addition, the Department of Health and Human Services is publishing this notice pursuant to section 7 of the Healthcare Research and Quality Act of 1999, Public Law 106-129, 42 U.S.C. 241 note, and section 247 of the Public Health Service Act, 42 U.S.C. 238p (as added by section 403 of the Public Health Improvement Act, Public Law 106-505).

The guidelines provide a general framework for initiating a design process for public access defibrillation (PAD) programs in Federal facilities and provide basic information to familiarize facilities leadership with the essential elements of a PAD program. The guidelines are not intended to exhaustively address or cover all aspects of AED or PAD programs. They are aimed at outlining the key elements of a PAD program so that facility-specific, detailed plans and programs can be developed in an informed manner.

FOR FURTHER INFORMATION CONTACT: Stanley C. Langfeld, Director, Real Property Policy Division (MPR), Room 6210, General Services Administration,

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1800 F Street, NW., Washington, DC 20405, telephone 202-501-1737. Arrangements to receive the policy guidelines in alternative format may be made by contacting the named individual.

Dated: May 15, 2001.
G. Martin Wagner,
Associate Administrator for Governmentwide Policy, General Services

Administration.

Arthur J. Lawrence,
Assistant Surgeon General, Acting Principal Deputy Assistant Secretary
for Health, Department of Health and Human Services.

Attachment--Guidelines for Public Access Defibrillation Programs in
Federal Facilities, January 18, 2001

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1.0 Purpose

The primary purpose of these guidelines is to provide a general framework for initiating a design process for a public access defibrillation (PAD) program in Federal facilities. A secondary purpose is to familiarize Federal agencies with the essential elements of such a program. The design of a PAD program in any Federal facility will be unique, and depend on many factors, including the population demographics of the facility/Federal area, and size and location of the facility/Federal area. The design process and key elements of a PAD program cited in these guidelines are intended to provide a foundation upon which individually tailored programs are developed and implemented.

This document is not intended to be a comprehensive summary of all aspects of automated external defibrillator (AED) use or PAD programs. Rather, it is aimed at providing sufficient information to understand the basic key elements of a program and to launch an effective planning and implementation process. There are numerous sources for training and education programs as well as model protocols that can be used at various stages in the planning. The required medical consultation can be obtained from Federal sources or private contractors.

2.0 General

Over the past several years, advances in technology have provided several innovative opportunities to prevent unnecessary disability and death. One of the most important of these advances is the AED. The ease of use of AEDs by the trained lay public has led to the increasing development of PAD programs. The decreased cost of acquisition and upkeep of AEDs now makes it possible to increase further the availability and access to these life-saving devices.

Ventricular fibrillation (VF) is a common arrhythmia leading to cardiac arrest and death. VF is unorganized electrical activity of the heart, resulting in producing no blood flow or pulse and which will lead to death. Defibrillation is the only technique that is effective in returning a heart in VF to its normal rhythm. Although defibrillation has been shown to be effective in correcting this abnormality in most cases, up until the advent of AEDs defibrillation has been a medical intervention only available to be performed by credentialed health professionals and trained emergency medical service personnel. While it is difficult to use an AED improperly, AEDs are not without risks if used improperly. AEDs are prescription devices that are intended to be operated only by individuals who have received proper training and within a system that integrates all aspects from first responder care to hospital care. Hence, a significant emphasis on proper training and linkage (notification or transfer) to emergency medical services (EMS) systems is critical. The value of the AED technology is that an AED will not energize unless an appropriate shockable cardiac rhythm is detected.

The efficacy of defibrillation is directly tied to how quickly it is administered. Although the outside limit of the "window of opportunity" in which to respond to a victim and take rescue actions is approximately 10 minutes, the sooner the AED is utilized within that time period, the more likely it is that it will be effective and that a patient will have a normal heart beat restored and fully recover. As the length of time between the onset of sudden cardiac arrest and defibrillation increases, the less the chance of restoration of heart beat and full recovery. In general, for every minute that passes between the event and defibrillation, the probability of survival decreases by 7 to 10 percent. After 10 minutes, the probability of survival is extremely low. The importance of rapid and positive intervention is reflected in the American Heart Association's (AHA) "Chain of Survival" concept.

Today's AEDs are relatively inexpensive and usable by persons with limited training. The advantage of well structured PAD programs is that they provide better trained individuals and increase accessibility, and, as a result, increase the potential to reduce response times and markedly increase the probability of survival and full recovery.

The "Chain of Survival" is designed to optimize a patient's chance for survival of sudden cardiac arrest. There are four links in the chain: early access, early cardiopulmonary resuscitation (CPR), early defibrillation, and early advanced cardiac life support (ACLS).

Early access means that members of the community have been trained to quickly recognize possible cardiac arrest and that a mechanism for immediate communication of the event and activation of an EMS response is in place to assure that fully trained EMS personnel and equipment can arrive quickly at the scene. Early CPR by bystanders provides ventilation and circulation, "buying" precious minutes for EMS teams to arrive with a full set of ACLS equipment. The core concept of the PAD strategy is to initiate CPR promptly and bring the defibrillator and a trained LayResponder/Rescuer (LRR) into the incident sooner than a fully equipped EMS unit can be on location.

The material in these guidelines is based upon the recommendations, programs, and literature on AEDs from the AHA and the American Red Cross (ARC), leaders in the encouragement of AED installation, training, and usage. The AHA and ARC cooperate with other organizations in developing and improving standards for AEDs. Users of this guidance should check the latest AHA, ARC, and National Safety Council (NSC) information for updates and/or changes in recommendations.

Special Note: As is the case in most clinical developments, the science-supporting efficacy in controlled settings usually precedes evidence of effectiveness when implemented large scale in real world settings. The science surrounding the effectiveness of AEDs,

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as well as the technology of AEDs themselves, is evolving.

For Federal agencies in GSA controlled space, the Designated Official should take reasonable steps to assure that a program's supervising physician reviews the facility's program on a regular basis in light of the most current scientific literature. The Designated Official is the highest-ranking official of the primary occupant agency of a Federal facility; or, alternatively, a designee selected by mutual agreement of occupant agency officials (see 41 CFR 101-20.003(g)). AED programs should evolve based on the best available science to assure the most efficient use of resources and the best outcomes possible. Federal sites implementing AED programs should strongly consider coordinating with, and becoming a component of, organized research or evaluation efforts in their communities. Assistance in determining if a facility is eligible to participate in such an effort can be obtained through the National Heart, Lung, and Blood Institute, AHA, American College of Emergency Medicine (ACEM) or the nearest research university/academic health center.

3.0 The Concept of Public Access Defibrillation (PAD)

Traditionally, EMS systems employ paramedic and emergency medical technician (EMT)--level personnel in conjunction with some level of involvement by community members, predominantly bystanders who are CPR trained. Most communities provide CPR training opportunities either through a local institution or via programs sponsored by units of a local or State/Territorial government. Until recently, AEDs and other defibrillation devices have been brought to locations by the local EMS system. The size, cost, and complexity of these devices, as well as other factors, have constrained their use. With recent advances in technology, many of the previous constraints have been reduced or eliminated. Increasingly, AEDs are being deployed in public facilities such as sports arenas, shopping malls, and airports, or in police and fire units, thus potentially decreasing the time between cardiac arrest and access to defibrillation.

However, optimal improvement in survival from sudden cardiac arrest that occurs in a non-medical setting may require a program that utilizes community "volunteer" lay responders or rescuers (non-medical LRRs), who have been trained in CPR and in the appropriate use of AEDs. A comprehensive, well integrated community approach to the use of AEDs would serve a large proportion of the community (a facility, a campus, etc.). LRRs could quickly respond to, identify, and treat a cardiac arrest patient and activate the formal EMS system.

"Public access" to AEDs does not mean that any member of the public who witnesses an event should be able to use an AED. "Public access" refers to the accessibility of the device itself. While AEDs are reasonably uncomplicated to use, the AED should be used only by

persons who have received proper training and education and who have been certified by a competent authority. Persons without these basic credentials should not use the device.

4.0 Establishing a PAD Program in a Federal Facility

Before establishing a program in a facility, each agency should enlist the assistance of not only the personnel at that location, but also local training, medical, and emergency response resources. These partnerships are fundamental to any successful PAD program. In some instances, a facility may be large enough to have training, medical, and emergency response resources integral to Federal operations. For the most part, this will be the exception rather than the rule, but the same principles apply. The more closely the PAD program is connected to such resources and the more visibility and support given to the program by the facility leadership, the more effective and successful will be the program.

Each PAD program should include the following major elements:

- Support of the Program by Agency Leadership
- Training/Certifying and Retraining Personnel in Cardiopulmonary Resuscitation (CPR) and the Use of the AED and Accessories

- Obtaining Medical Direction and Medical Oversight

- Understanding Legal Aspects

- Development and Regular Review of PAD and Operational Protocols

- Development of an Emergency Response Plan and Protocols, Including a Notification System to Activate Responders

- Integration with Facility Security and Emergency Medical Services (EMS) Systems

- Maintaining Hardware and Support Equipment on a Regular Basis and After Each Use

- Development of Quality Assurance and Data/Information Management Plans

- Development of Measurable Performance Criteria, Documentation and Periodic Program Review
- Review of New Technologies

It is important to emphasize that PAD programs are not isolated "one time events." PAD programs should be reviewed on a regular basis and improved where possible. Additionally, after every incident involving use of the PAD system, a thorough post-event review of system performance should be undertaken. The skills of personnel who are potential responders and rescuers should be refreshed and new personnel trained. The program should make an effort to routinely and regularly assess the operating state and condition of AED and support equipment as well.

A key element in assuring that your PAD program will be clearly understood and will function well is the development of standard operating procedures (SOPs) for the major components of the program. SOPs, as well as the program as a whole, should be periodically revisited and revised where appropriate.

5.0 Designing a PAD Program

Given the wide variation in Federal work facilities, there will be significant variation in the complexities associated with program design. Small, physically compact offices will require different levels of planning and design than large, multi-building facilities spread over campus environments. Facility leadership should take steps to assure that all stakeholders, including those who are external to the

facility, are afforded the opportunity to participate in planning and design. Although it is possible to have the full range of planning and design activities performed via consultant or contract, it should be kept in mind that the actual responders at a facility typically will be those who work there and that both individual employees' and unions' interests, in accordance with union contracts, should be considered in any process. Officials in the facility's management "chain of command" must have close involvement at every step, as specified for occupants of facilities under GSA custody and control in 41 CFR 101-20.103-4, entitled "Occupancy Emergency Program."

While most Federal agencies' facilities are single tenant buildings or may have several tenants under the clear command/leadership of a ranking official, many GSA facilities contain multiple tenants that are not under the direction of a single agency official. 41 CFR 101-20.103, entitled "Physical protection and building security," provides guidance on coordinating and implementing a comprehensive Occupancy Emergency Program. (The definition of "emergency" in this part

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(see 41 CFR 101-20.003(i)) includes medical emergencies.) In facilities that are multi-tenant, special attention should be paid to avoid confusion about decision-making processes and authority for the development and operation of a PAD program. It is recommended that the Federal agencies in multi-tenant circumstances follow the guidelines described in 41CFR 101-20.103 to assure clarity of responsibility and accountability.

Because Federal law enforcement officers routinely respond to emergencies within Federal properties and are familiar with all sites within their jurisdiction and are required to be first aid and CPR trained, it is recommended that all Federal Police Officers also receive the necessary training in the use of AEDs. Federal agencies should also consider the security implications of training contract guards in the use of AEDs since these guards have responsibilities to guard entry points and other fixed posts within a facility. The security implications of contract guards abandoning these posts during a medical emergency should be carefully considered in the development and operation of a PAD program.

We recommend that Automated External Defibrillator response orders be included as part of each facility's Occupant Emergency Plan. See ATTACHMENT A, entitled "SAMPLE AED PROTOCOL AND RESPONSE ORDER ELEMENTS."

6.0 Selecting Your AEDs

Only commercially available AEDs that have been cleared for marketing by the Food and Drug Administration (FDA) should be considered for use in a PAD program. Prior to purchasing, it is important for facility leadership to seek assistance in the selection of a device for deployment in the facility. Because technology is developing quite rapidly, seeking the advice of an individual or organization with current knowledge about AEDs is essential. Involving a medical oversight provider(s) is crucial.

Additionally, as there are some differences in the devices currently on the market, an expert can help to explain the relative advantages and disadvantages of AEDs for your particular location. Utilizing a single brand of AED within a facility will greatly simplify training, maintenance, and data management. It would be wise to contact local EMS personnel to seek their opinion and to clarify protocols with

respect to equipment use.

Currently, there are Federal Supply Service (FSS) Supply contracts for AEDs. A prescription from a physician overseeing the AED placement must accompany the order before the AED manufacturer can accept the order and deliver the AED. Your procurement office can assist in locating current contract information and prices.

In the future, additional products are likely to receive approval for marketing from the FDA. Program designers should take steps to confirm that all devices that are acquired have received FDA marketing approval and that the use of AEDs in their respective facilities fully complies with FDA labeling requirements.

Special Note: AEDs are prescription devices. In a PAD program, plans and protocols that are approved by a supervising physician are considered a prescription. The selection of a particular AED and associated equipment are integral components of a PAD program. Once the physician has approved and signed-off on AED selection and placement, this becomes the authorizing prescription for procurement of the device(s).

Emergency response and AED usage protocols that are signed by a physician are a prescription constituting legal "permission" for properly trained and certified individuals to use AEDs in a particular manner as outlined in the protocol. Responders must be familiar with and trained in the context of the approved procedures in the facility and strictly adhere to these procedures when an emergency occurs.

The actual selection and procurement of AEDs should be one of the last steps in the design of a facility's PAD program and should be done under the guidance and written authorization of the PAD program's supervising physician. The protocol for AED usage that is developed as part of a facility's PAD program is an integral part of the physician's prescription and serves as the authorizing document for AED use. Protocols should be periodically reassessed in accordance with a regular schedule of reviews as determined in consultation with the PAD's supervising physician. A current protocol that takes into consideration both new treatment recommendations and any changes in the FDA labeling of the AED should be integrated into the PAD training and education and re-training programs.

Essentially, the protocols that are signed by the supervising physician set the medical standards and criteria for the operation of the PAD program and all of its components. Systems operated within the boundaries and criteria of these signed protocols are considered to be under a physician's supervision, whether or not the physician is physically present in the facility. As noted in this guidance, PAD programs should be reviewed on a regular basis (after each activation and/or on a regular basis) with changes made as needed under the direction of the supervising physician. These revised or re-certified protocols constitute new or renewed prescriptions.

7.0 Medical Oversight of Your PAD Program

AEDs are medical devices that are to be used under the advice and consent of a physician only by individuals with the proper training and certification. Therefore, medical oversight is an essential component of PAD programs. This oversight can be provided either by a facility's own medical staff, such as a Health Unit, or contractor or through an agency-wide designated Federal physician in accordance with state and local laws. It is best to seek medical input from the very beginning of

the design of your program. A physician should be involved as a consultant in all aspects of the program, not only as the program's prescribing physician, but also as an active participant in all aspects.

Medical and physician oversight does not mean that a physician is required to be present to manage the PAD program on a day-to-day basis. However, it is prudent for facility leadership to develop management and oversight protocols of lay program overseers to assure that quality is consistently maintained. Physicians can be extremely helpful in assisting facility leadership in linking their PAD program with the community at large and with appropriate EMS and hospital systems. Additionally, a central role for the physician is conducting assessment of the PAD system's performance after the use of an AED, including review of the AED data and the electrocardiogram tracing of a victim.

8.0 Legal Issues

Any PAD program should be reviewed by legal counsel to assure that the program, as designed, comports with all applicable Federal, State and local authorities. PAD programs establish procedures for dealing with emergent medical situations that present an appreciable risk of serious bodily injury and death regardless of the degree of care exercised by those involved in responding to the situation. These situations are often the subject of regulation by various authorities. The risk of liability for failing to comport with applicable regulations, and for acts or omissions that result in harm, are important and ever-present concerns that should be addressed in the PAD program. Though federal facilities

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generally are not subject to state and local authority, federal law can incorporate or adopt specific state and local authorities or otherwise make them applicable to federal facilities.

One of the most important legal concerns with any PAD program will be the potential liability of those who respond to the emergent situation, including, potentially, Federal employees. The following principles should be considered in developing a PAD program:

As a general rule, the Federal Tort Claims Act, 28 U.S.C. sections 1346(b), 2671-80, (FTCA) immunizes Federal employees acting within the scope of the employment from personal liability for most tortious conduct. Whether an individual Federal employee was acting within or without of the scope of his/her employment is, under the FTCA, determined by the substantive law of the state where the act or omission occurred. Employees whose use of an AED is outside the scope of their employment may be eligible for federal representation, but could be personally liable for any harm that results from the use of the AED.

The liability of the Federal government for injuries caused by Federal employees acting within the scope of their employment is determined by the FTCA as well. The FTCA, provides that liability is determined according to the law of the place where the wrongful or negligent act or omission occurred. Under the FTCA, the Federal government is not liable for the wrongful acts of any person who is not a "Federal employee," defined in 28 U.S.C. section 2671.

Under the FTCA, the United States is not liable for the wrongful acts of government contractors. Thus, a PAD program should consider reposing responsibility for responding to emergency medical situations on a contractor over which we do not exercise day-to-day control. The PAD program should, however, include criteria to assure

that the contractor has the requisite expertise, training and resources.

Many states have enacted legislation to provide some degree of immunity to lay individuals who provide assistance to people in distress. The laws are called "Good Samaritan" laws. Because these laws vary from state to state, management of individual facilities should be aware of the law applicable to them. Attachment B (entitled "Draft Summary of Legislative Activity by State as of June 1, 2000") is a recent abstract of state/territorial "Good Samaritan" laws.

Congress recently provided additional protection from civil liability for AED use in the Public Health Improvement Act, Public Law 106-505 (November 13, 2000). Subtitle A of Title IV of the Act, the Cardiac Arrest Survival Act of 2000, provides persons who use or attempt to use an AED, and persons who acquire an AED, immunity from civil liability for harms resulting from the use or attempted use of the AED, subject to a number of important exceptions. The statute provides a default immunity only, however: the federal immunity displaces a State rule of decision only to the extent that State has no statute or regulations that provide users or acquirers with immunity for civil liability arising from emergent use of an AED. The statute explicitly states that its provisions are not intended to waive any protections from liability for Federal officers and employees provided in the FTCA or Westfall Act.

Nothing in these guidelines or in any PAD program established pursuant to these guidelines should be read as creating a duty for Federal employees or contractors not otherwise existing under applicable state or Federal law to provide assistance to persons in medical distress.

9.0 Lay Responder/Rescuer (LRR) Training

Even in the case where large facilities have self-contained emergency medical services systems, it is still advisable to devise a training program for LRRs. The greater the number of well trained LRRs that are available, the more effective a PAD program will be. Overall effectiveness will be improved as the number of personnel who are fully trained and willing to respond increases. As a general matter, in facilities where there are sufficient numbers of personnel to permit in-house training programs, a routine training schedule should be established. An additional benefit of in-house training is that training in groups that correspond closely with work groups tends to build a better sense of team and responsibility than would individual, separate training.

Nationally recognized training organizations such as the AHA, ARC, and NSC, provide materials and guidance through a variety of courses that include combined CPR and AED training. These programs provide comprehensive materials for the training of LRRs and are targeted toward providing lay persons all of the information and training necessary to competently assess the status of a victim, administer CPR if necessary, and to properly operate an AED. It is important for LRRs to be trained on the maintenance and operation of the specific AED model that will be used in their PAD program.

Some locales may wish to take an additional step and organize their responses around a team approach. The recommended training course provides flexible training and will incorporate elements of 2-person rescue techniques that accommodate a "response team" approach.

All PAD training programs should include a component that describes and explains the facility specific program. All retraining or refresher programs should, likewise, include this component to assure that LRRs are aware of the most current information regarding their specific PAD

program.

Training is not a one-time event. Leadership should seek to maintain and improve the LRRs' skills and abilities. Formal refresher training should be conducted at least every two years. Computer-based programs and video teaching materials permit more frequent review. Facility leadership should make periodic contact with the AHA to assure that advances in techniques and care are incorporated into their PAD program, and training in them is promptly made available to LRRs. It is recommended that LRR teams engage in periodic "scenario" practice sessions to maintain their skills and rehearse protocols.

Facility leadership is urged to develop a vigorous approach to maintaining and improving skills. Thus, aside from formal annual recertification, mock drills and practice sessions will be important to maintain current knowledge and a reasonable comfort level among LRRs and/or teams. The frequency of such sessions will vary from facility to facility. Organizations currently operating PAD programs routinely complete practice sessions on a monthly to quarterly schedule. The intervals for conducting these exercises should be established in consultation with the physician providing medical oversight.

10.0 Placement of and Access to AEDs

While there is no single "formula" to determine the appropriate number, placement, and access system for AEDs, there are several major elements that should be considered. However, all considerations are based upon (1) an optimal response time of 3 minutes or less and (2) assessing the level of risk in a facility's environment. Factors that should be considered include:

Response Time: The optimal response time is 3 minutes or less. This interval begins from the moment a

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person is identified as needing emergency care to when the AED is at the side of the victim. Survival rates decrease by 7 to 10 percent for every minute that defibrillation is delayed. Therefore, it is recommended that Federal agencies train as many employees as possible on the use of AEDs.

Demographics of the Facility's Workforce: Leadership should examine the make up of the resident workforce. Because the likelihood of an event occurring increases with age, consideration should be given to the age profile of the workforce.

Visitors: Facilities (including Federal areas, such as Wilderness Areas and National Parks) that host large numbers of visitors are more likely to experience an event, and an appraisal of the demographics of visitors should be included in an assessment.

Specialty Areas: Facilities where strenuous work is conducted are more likely to experience an event. Additionally, specialty areas within facilities such as exercise and work out rooms should be considered to have a higher risk of an event than areas where there is minimal physical activity.

Physical Layout of Facility: Response time should be calculated based upon how long it will take for an LRR with an AED walking at a rapid pace to reach a victim. Large facilities and buildings with unusual designs, elevators, campuses with several separate buildings, and physical impediments all present unique challenges to LRRs. In some larger facilities, it may be necessary to incorporate the use of properly equipped "golf cart" style conveyances to accommodate time and distance conditions.

Physical Placement of AEDs: Facilities that have large

open areas present unique challenges.

11.0 Characteristics of Proper AED Placement

There are several elements that contribute to proper placement of AEDs. The major elements are:

- An easily accessible position (e.g., placed at a height so those shorter individuals can reach and remove, unobstructed access, etc.)

- A secure location that prevents or minimizes the potential for tampering, theft, and/or misuse, and precludes access by unauthorized users.

- Facilities should take additional steps to assure that an AED has not been stolen or improperly removed.

- A location that is well marked, publicized, and known among trained staff. Periodic "tours" of locations are recommended.

- A nearby telephone that can be used to call backup, security, EMS, or 911 to be sure that additional help is dispatched.

Protocols should clearly address procedures for activating local EMS personnel. These protocols should include notification of EMS personnel of the quantity, brands, and locations of AEDs within the facility. This information will enhance dispatch and the EMS responder protocol, enabling proper planning and scene management once EMS personnel arrive at the victim's side. Equipment stored in a manner in which the removal of the AED automatically notifies security, EMS, or a central control center is ideal.

Where automatic notification of the opening of an AED storage cabinet or removal of an AED from a cabinet is not implemented, emphasis should be placed on notification procedures and equipment placement in close proximity to a telephone.

Equipment To Be Placed With AEDs

It is recommended that additional items that may be necessary to a successful rescue be placed into a bag and be stored and accessible with the AED. Keep in mind that CPR is an essential element of an effective rescue and that as a victim collapses, other physical injury may occur concurrently:

- A set of simplified directions for CPR and the use of the AED

- Non-latex protective gloves (several pairs in small, medium, and large sizes)

- Appropriate sizes of CPR face masks with detachable mouthpieces, plastic or silicone face shields (preferably clear), with one-way valves, or other type of barrier device that can be used in mouth to mouth resuscitation

- Disposable razor to dry shave a victim in chest areas if needed, as well as a supply of 4x4 gauze pads to clear/dry an area, to assure proper electrode-to-skin contact

- A pair of medium size bandage or blunt end scissors

- Spare battery and electrode pads

- Two biohazard or medical waste plastic bags for waste or for transport of the AED should it become contaminated

- Pad of paper and writing tools

- One absorbent towel

In large or complex facilities, access routes should be given careful consideration. Such facilities may demand the use of a designated responder or team approach, in which at least one responder has keys or passes to allow for the use of a more direct or elevator override key to expedite access and transport by appropriate medical or

EMS personnel.

12.0 Follow-Up After an AED Is Used

All AEDs are equipped with a credit card size device (e.g., data card) or have the capacity to internally store data for later downloading, that will record and contain information about the patient's heart rhythm, AED assessment functioning, and the characteristics of the shock(s) administered. Depending on the design of a particular PAD, the AED will either accompany the victim to the hospital or will be retained on site for the medical advisor of the PAD's review. The proper disposition of the AED and its electronic recorder module must be addressed in a PAD program's protocols.

After an event, the PAD medical director should be promptly notified, and a review and assessment of performance should be performed. This process is best led by the PAD's physician overseer. A copy of the full report should be provided to and reviewed by the Designated Official and any other authorities, as required by state and local laws.

Incident reports and follow-up should be performed as soon as possible, and restocking of supplies and returning the AED to service should be accomplished. All aspects of the performance of the system, people, device, and protocols should be addressed in a non-judgmental manner with an eye toward verifying or improving effectiveness and to identify problem areas that must be resolved. Responsibility for each step should be clearly articulated in protocols. The results of routinely scheduled and post event reviews should be shared and discussed with facility management and other interested parties as deemed appropriate in a particular facility. Individuals with responsibility for facility oversight are also responsible for the PAD program and should remain informed about their program's performance.

Post event reviews should be arranged and conducted with sensitivity to issues of medical and patient record confidentiality. As such, the physician overseeing the PAD program should conduct a thorough medical documentation review prior to the "process" evaluation that will be conducted by or for individuals with responsibility for facility management. The physician should be charged with assuring that privileged or confidential patient information is shielded.

An essential post-event consideration is the psychological effect on LRRs and others. It is not at all uncommon for LRRs, witnesses, and co-workers to have

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psychological or stress reactions to an event. These people may have both emotional and physical reactions that need to be tended to, but for which there is a reluctance to come forward to ask for help. Facility leadership has a positive obligation to pro-actively reach out and offer help, affirming that such responses are normal and to a large extent to be expected. Post-event support is especially important in cases where a rescue is unsuccessful. Post-event support should be available and offered promptly after an event, and the invitation to seek assistance should remain open. This type of psychological care is best provided by trained professionals with expertise in the area of critical incident stress management. Provision of these psychological services should be addressed in the PAD program design and protocols.

Attachment A.--Sample AED Protocol and Response Order Elements

Activation of the AED Response Team

1. During Health Unit Duty Hours: 7 a.m. to 12 a.m. Monday through Friday; weekends and Federal holidays, the health center is closed. In any potentially life-threatening cardiac emergency:

- (a) The first person on the scene will:
 - (i) Call the Security Console by dialing ``0000`` and inform them of the location and nature of the emergency.
 - (ii) Remain with the victim, send a co-worker to meet the emergency team at a visible location and escort to the site.
 - (b) Security Personnel immediately upon receiving the call will:
 - (i) Notify the AED response team by dialing the group notification number for the AED team pagers; Enter the code for the location of the emergency.
 - (ii) Notify local EMS 911.
 - (iii) Inform the EMS operator of location and nature of emergency and that an AED unit is on site.
 - (iv) Notify Federal Police Officer(s) to meet the EMS personnel and escort them to the site of the emergency.
 - (v) Notify Federal Police Officer(s) to respond to the site and offer any assistance needed (if staffing allows).
 - (c) Health Unit Staff immediately upon receiving the notification will proceed directly to the scene with the Health Unit AED and other emergency equipment (2 nurses will respond if available).
 - (d) Other AED responders immediately upon receiving the notification will:
 - (i) (The team member previously designated to transport the AED unit) obtain the AED unit closest to them or to the site of the emergency and proceed with it to the emergency site.
 - (ii) (All other AED responders) go directly to the site of the emergency.

Emergency Site Protocol

- Whichever AED responder arrives on the scene first will assess the victim. If AED use is indicated, the AED trained personnel will administer the AED and CPR according to established protocols (see Automated External Defibrillation Treatment Algorithm).
- When the Health Unit Nurse is on the scene, he/she shall be in charge of directing the activities until the local EMS arrives and assumes care of the victim.
- Any additional AED responders shall assist with CPR, recording of data and time, notifications, crowd control, escorting of EMS, as needed. Any additional AED units will remain on site as a back-up.

2. Non-Health Unit Hours: 12 a.m. to 7 a.m. Monday through Friday, and All Hours Saturday and Sunday and Federal holidays. In any potentially life-threatening cardiac emergency:

- (a) The first person on the scene will:
 - (i) Call the Security Console by dialing, ``0000`` inform them of the location and nature of the emergency.
 - (ii) Remain with the victim, send a co-worker to meet the emergency team at a visible location and escort to the site.
 - (e) Security Personnel immediately upon receiving the call will:
 - (i) Notify the AED response team by dialing the group notification number for the AED team pagers, enter the code for the location of the emergency.
 - (ii) Notify local EMS 911.
 - (iii) Notify Federal Police Officer(s) to meet the EMS personnel and escort them to the site of the emergency.

(iv) Notify Federal Police Officer(s) to respond to the site and offer any assistance needed (if staffing allows).

(c) AED Responders immediately upon receiving the notification will:

(i) (The team member previously designated to transport the AED unit) obtain the AED unit closest to them or to the site of the emergency and proceed with it to the emergency site.

(ii) (All other AED responders) go directly to the site of the emergency.

(iii) (Whichever AED responder arrives on the scene first) assess the victim. If AED use is indicated, the AED trained personnel will administer the AED and CPR according to established protocols (see Automated External Defibrillation Treatment Algorithm) until local EMS professionals arrive and assume care of the victim.

Attachment B

Draft Summary of Legislative Activity by State as of June 1, 2000

47 States Provide Limited Immunity for Lay Responders

1. Alabama--6/99
2. Alaska--4/98
3. Arizona--5/99
4. Arkansas--2/99
5. California--7/99
6. Colorado--3/99
7. Connecticut--10/98
8. Florida--4/97
9. Georgia--3/98
10. Hawaii--5/98
11. Idaho--3/99
12. Illinois--8/99
13. Indiana--2/99
14. Iowa--2/98--*Administrative rules or regulations allow AED use by laymen and provide immunity
15. Kansas--3/98
16. Kentucky--2/2000
17. Louisiana--6/99
18. Maryland--4/99
19. Massachusetts--11/99* strengthened 5/98 law
20. Minnesota--3/98
21. Michigan--11/99
22. Mississippi--3/99
23. Missouri--3/98
24. Montana--4/99
25. Nebraska--4/99
26. Nevada--6/97
27. New Hampshire--7/99
28. New Jersey--3/99
29. New Mexico--4/99
30. New York--8/98
31. North Dakota--3/99
32. Ohio--11/98
33. Oklahoma--4/99
34. Oregon--6/99
35. Pennsylvania--12/98
36. Rhode Island--95
37. South Dakota--2/00
38. South Carolina--6/99
39. Tennessee--5/99* strengthened 5/98 law

40. Texas--6/99
41. Utah--3/99
42. Vermont--5/00
43. Virginia--3/99
44. Washington--6/98
45. Wisconsin--7/99
46. West Virginia--3/99
47. Wyoming--3/99

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